Attorney Docket No.: 6516.200-US
Application Serial No.: 10/679,631
Filed: October 6, 2003
Title: Needle Insertion Device
Via Facsimile No.: 571-273-8300

REMARKS

Claims 1-16 are pending. The Office Action of June 29, 2005 rejected independent claim 1 and dependent claims 2-16 under 35 USC 103(a) as being unpatentable over **Alex et al.** (US patent 5,931,814) in view of **Gross et al.** (US patent 5,527,288) and/or **Kochamba** (US patent 6,896,666). Applicant respectfully disagrees with this finding for the following reasons.

Having regard to the cited art, it appears the Examiner considers the skin-mountable device disclosed in **Alex et al.** to represent a relevant starting point for the present invention.

Alex et al. discloses a skin-mountable drug delivery device comprising a housing with a lower surface and a needle. Alex et al. discloses two distinct embodiments as shown in fig. 1 respectively fig. 2.

In the fig. 1 embodiment the needle is arranged in a projecting position relative to the general plane of the mounting surface as seen in fig. 1 (i.e. as defined by the outer main portion of the mounting surface relative to which the protective sleeve moves), the device comprising protective sleeve 5 which can be moved relative to the main portion of the mounting surface to thereby expose the needle. It should be noted that the needle is fixedly arranged in the holder 12 and thus not moved by the lever 6.

Thus, the fig. 1 embodiment fails to disclose a needle arranged inside the device relative to the first portion of the mounting surface defining the general plane (feature (e)), just as it fails to disclose adhesive means arranged on the lower surface of the protective sleeve (feature (c)).

In the fig. 2 embodiment the needle is in an initial condition arranged such that the distal pointed end does not protrude relative to the general plane as defined by the base plate 24 in its initial position (dotted lines), whereas it protrudes from base plate when the latter is retracted (full line).

As appears, the fig. 2 embodiment fails to disclose a mounting surface with a second portion having a needle aperture formed therein and being moveable relative to a first portion (base plate 24) of the mounting surface (features (a) and (e)) in order to expose the needle, just as it fails to disclose adhesive means arranged on a lower surface of a second moveable portion (feature (c)).

Non-obviousness over the cited art in respect of claim 1

One advantage of the present invention is that it provides a skin-mountable needle insertion device which reduces the likelihood that a user comes into contact with an infusion needle or any other transcutaneously insertable structure prior to use or when the device is removed from the skin of the user after a period of use, see page 4, lines 26-29. This is neither disclosed nor taught or hinted at in **Alex et al.** or any other document on record.

According to the invention as defined in present claim 1, this advantage is accomplished by the features of claim 1 providing a mounting surface with a second portion moveable relative to a first portion between a first position in which the pointed end of a needle is arranged within the housing relative to the second portion, and a second position in which the pointed end of the needle projects through the needle aperture.

By this arrangement the risk of accidental contact with a needle or similar structure is reduced as the needle as such is arranged inside the device, i.e. the distal pointed end is arranged such that it does not protrude from the lower skin-contacting surface as defined by the general plane of that surface – neither in its enclosed nor in its exposed state, see figs. 3 and 5 of the exemplary embodiments. As the needle does not protrude from the lower surface as defined by the general plane, normally no insertion could take place when the device is mounted onto the skin of the user, however, corresponding to the invention as defined in claim 1, the skin portion corresponding to the intended site of needle insertion is pulled up against the needle by adhesive means arranged thereon.

Applicant submits that the concept of pulling a portion of the skin into the device in order to insert a needle through the skin of a subject substantially differs from what is disclosed and taught in the cited art.

More specifically, **Gross et al.** discloses a skin-mountable device having a needle protruding permanently from a unitary planar lower surface comprising an adhesive. Although the device thus comprises an adhesive surface covering the lower surface, there is no teaching that any advantages can be achieved by also providing an adhesive surface on a second, moveable portion of a mounting surface with an adhesive. In fact, as **Alex et al.** discloses a device having a first adhesive surface and a second non-adhesive surface in close proximity to each other, it can be argued that the disclosed configuration of the adhesive surfaces is not merely "by chance" but deliberately serves the intended purpose, thus teaching away from any modification thereof.

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However, even in the unlikely event that the skilled person should contemplate providing the protective sleeve of **Alex et al.** with an adhesive lower surface, such a combination would still not provide Applicants device as defined in claim 1. More specifically, as also pointed out above, the present invention as defined in claim 1 provides a device wherein the distal pointed end is arranged such that it does not protrude from the lower skin-contacting surface as defined by the general plane of that surface – neither in its enclosed nor in its exposed state. In contrast, **Alex et al.** discloses a needle device comprising a lower surface (either the protective sleeve of fig. 1 or the lower surface of fig. 2) which is moveable between an extended and a retracted position to respectively hide and expose a needle. From the point of the user, the result is that the needle will be fully protruding from the lower surface of the device when the device is removed from the skin of the user with the needle exposed.

In contrast, the present invention provides a needle device with a needle which "inherently" has a needle in a retracted position, the skin being moved towards the needle.

Turning to **Kochamba**, this document discloses a device comprising a unitary lower non-adhesive surface having a concave configuration, the device being adapted to be connected to a suction source for moving a skin portion of a subject into the concave portion of the device. However, in contrast to the present invention providing a second surface mounting portion moveable relative to a first surface mounting portion, **Kochamba** provides a unitary mounting surface in combination with a moveable needle which is inserted through the skin after the skin has been pulled into contact with the concave surface by means of a supplied vacuum, e.g. compare figs. 1 and 2 of **Kochamba**. In other words, **Kochamba** provides a vacuum operated system for fixing a device relative to a raised skin surface, however, needle insertion takes place in the conventional way by introducing a moveable needle through a non-moving portion of the skin.

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Thus, even in the extremely unlikely situation that a person would contemplate combining the different features and teachings of the three cited documents **Alex et al.**, **Gross et al.** and **Kochamba.**, such a combination would still not provide the present invention as defined in claim 1.

Conclusion

As neither the problem identified by the present Applicant (i.e. providing a simple needle device which is inherently safe in use both prior to use and when the device is removed from the skin), nor the corresponding solution (i.e. arranging the needle inside the housing relative to a first mounting surface portion and providing a mounting surface with an adhesive second portion having a needle aperture formed therein and being moveable relative to the first portion) is known from or taught by the cited documents, it follows that the skilled person would neither have incentives nor a teaching to modify the needle devices known from the cited art in order to provide a needle device as defined in claim 1, nor would (s)he be provided with the solution to the problem.

More specifically and having regard to the above presented arguments, the three cited documents fail, either taken as a single document, a combination of two documents, or as a combination of all three documents, to provide or teach to the skilled person a device in which a needle is arranged inside a housing relative to a first portion of a mounting surface, the device further comprising a second portion of the mounting surface moveable between a first position in which the pointed end of a needle is arranged within a housing relative to the second portion, and a second position in which the pointed end of the needle projects through a needle aperture arranged in the second portion.

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In addition to the above, **Gross et al.** fails to provide a teaching to the skilled person that the adhesive of a unitary skin mounting surface advantageously should be applied to a second, moveable portion of a mounting surface as known from **Alex et al.**, just as **Kochamba** fails to disclose or teach that a skin portion should be moved into contact with a structure (let alone a needle) by means of an adhesive.

In view of the above, it is respectfully submitted that all outstanding issues raised by the Examiner have been addressed and therefore all claims are in condition for allowance. Reconsideration is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner should feel free to contact applicant's attorney by telephone if there are any questions concerning this reply or application.

Respectfully submitted,

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